UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- CENTERS FOR DISEASE CONTROL AND PREVENTION AND HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No. 1:21-cv-1179

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, as for its Complaint regarding Freedom of Information Act requests against the above-captioned Defendants, alleges as follows:

INTRODUCTION

1. Between December 2020 and February 2021, the Food and Drug Administration ("**FDA**") issued Emergency Use Authorizations for three COVID-19 vaccines,[1] one of which subsequently received FDA approval in August 2021.[2] While the FDA approved these vaccines, the Centers for Disease Control and Prevention ("**CDC**"), an agency within the Department of Health and Human Services ("**HHS**"), is charged with monitoring the safety of all vaccines, including the COVID-19 vaccines approved by the FDA. The CDC claims that these "COVID-

[1] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (last visited December 23, 2021); https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (last visited December 23, 2021); https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine (last visited December 23, 2021).

[2] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited December 23, 2021).

19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history[.]**"[3]

2. The federal government has mandated that millions of Americans receive these vaccine products. HHS has also given pharmaceutical companies complete immunity for injuries caused by those products. Mandating that millions of Americans inject a product for which they cannot hold the manufacturer liable if the product injures them demands complete **transparency**, especially when it comes to releasing the data underlying the product's safety. FOIA exists precisely so that the American people can obtain transparency and, in this case, obtain the data which supports the CDC's claims to intensive safety monitoring.

3. As for the pre-licensure data submitted by the pharmaceutical companies, the FDA took the position in another FOIA action that, because it needs to deidentify that data, it needs at least 75 years to produce the data to the public.[4] As for the post-licensure data, the FDA and CDC have said that their prior primary existing safety monitoring program was incapable of determining causation and were otherwise unreliable. The CDC has, however, deployed a new safety monitoring system for the COVID-19 vaccines, v-safe, and the data within v-safe is already available in deidentified form and could be forthwith released to the public.

4. V-safe is a smartphone app that allows vaccine recipients to "tell CDC about any side effects after getting the COVID-19 vaccine."[5] The purpose of the app "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting

[3] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (last visited December 27, 2021).

[4] *See Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, 4:21-cv-01056-P (N.D. Tex.), ECF Nos. 29 and 31.

[5] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html (last visited December 23, 2021).

and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[6]

5. Data submitted to v-safe is "collected, managed, and housed on a secure server by Oracle,"[7] a private computer technology company. Although the CDC has "access to the individualized survey data," Oracle can only access "**aggregate deidentified data** for reporting."[8]

6. Plaintiff asked through its instant FOIA requests that the CDC produce the deidentified data from the v-safe program in the same form that Oracle can access. Plaintiff believes that to assure transparency regarding the government's claim that COVID-19 vaccines are "safe and effective,"[9] the public should have immediate access to all v-safe data, in deidentified form, and therefore, once the CDC produces that data, Plaintiff intends to make it publicly available. Despite the fact that the deidentified data already exists, it is already in the hands of a private company, and the CDC has never objected to its production, the CDC has so far failed to produce it to Plaintiff or to the American public. The federal government is thereby not only failing to provide the transparency necessary to earn the American people's trust regarding these vaccines but is also failing to comply with FOIA.

7. Plaintiff Informed Consent Action Network ("**Plaintiff**") is a non-profit organization that advocates for informed consent and full transparency and disseminates

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[6] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf (last visited December 20, 2021).

[7] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf p. 8 (last visited December 23, 2021).

[8] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf p. 9 (last visited December 23, 2021) (emphasis added).

[9] *See, e.g.*, https://www.fda.gov/media/146269/download (materials for February 26, 2021 meeting of the Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**") stating "[r]eactogenicity profiles of mRNA vaccines in v-safe monitoring are consistent with what was observed in clinical trials") (last visited December 8, 2021); https://www.fda.gov/media/150054/download (materials from June 10, 2021 meeting of VRBPAC stating "[i]nitial safety findings from Pfizer-BioNTech COVID-19 vaccination of 12-15-year-olds from v-safe and VAERS surveillance are consistent with results from pre-authorization clinical trials"); https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (materials from October 21, 2021 meeting of Advisory Committee on Immunization Practices stating "[n]o unexpected patterns of adverse events were identified").

information necessary for same with regard to all medical interventions. It intends to make all v-safe data immediately available to the public so that independent scientists can immediately analyze that data. It believes that we need all hands on deck, both inside and outside the government, to address serious and ongoing issues with the vaccine program, including waning immunity, adverse reactions, etc. Locking out independent scientists from addressing these issues is dangerous, irresponsible, unethical, and illegal.

8. To acquire the v-safe data, Plaintiff made three requests to the CDC pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**") seeking information regarding v-safe.

9. Plaintiff's first request was for "[a]ll de-identified data submitted to v-safe since January 1, 2020" (the "**First Request**"). The CDC issued a final response acknowledging that the data exists, but it did not produce any data, despite the fact that Oracle has aggregate, de-identified data, because "information in the app is not deidentified." Plaintiff appealed the CDC's response to HHS, including pointing out to the CDC that its own documentation regarding v-safe explains that "Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, **will have access to aggregate deidentified data for reporting**," and hence that deidentified data should be produced to the public forthwith. Neither the CDC nor HHS has substantively responded to that appeal.

10. Plaintiff's second request was for "[a]ll documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same" (the "**Second Request**"). The CDC produced some documents to Plaintiff, but notably failed to produce any communications. Plaintiff therefore submitted an administrative appeal to HHS. Neither the CDC nor HHS has substantively responded to that appeal.

11. Plaintiff's third request was submitted in order to clarify any misunderstanding about the First Request and sought "all data submitted to v-safe and subsequently deidentified . . . from January 1, 2020 forward" (the "**Third Request**"). Again, despite the fact that Oracle has this de-identified data, the CDC has not produced any documents in response to the Third Request and instead administratively closed it.

12. Plaintiff brings this action to challenge the CDC and HHS' failure to produce all responsive documents, the CDC and HHS' failure to timely respond to its appeals, and the CDC's administrative closure of the Third Request.

PARTIES

13. Plaintiff is a not-for-profit organization with an office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705.

14. The CDC is an agency within the Executive Branch of the United States Government, organized within HHS. The CDC is an agency within the meaning of 5 U.S.C. § 552(f).

15. HHS is an agency within the Executive Branch of the United States Government. HHS is an agency within the meaning of 5 U.S.C. § 552(f).

JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

A. COVID-19 Vaccines

17. In December 2020, the FDA issued emergency use authorizations for the Pfizer-BioNTech[10] and Moderna[11] COVID-19 vaccines. In February 2021, the FDA issued an emergency use authorization for the Janssen COVID-19 vaccine.[12] There have been subsequent emergency use authorizations issued for these three vaccines for younger age groups, for boosters, and for "mix and match" administration of the three vaccines. In August 2021, the FDA licensed the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older.[13]

18. Although all three novel COVID-19 vaccines available in the United States were developed at record pace, these products are being mandated for a majority of Americans under the threat of losing their jobs, being separated from the military, being excluded from university, and from participating in civil society.[14] The federal government has, for example, issued mandates for private employees, public employees, and the military.[15] Some cities have gone as

[10] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (last visited December 23, 2021).

[11] https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (last visited December 23, 2021).

[12] https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine (last visited December 23, 2021).

[13] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited December 23, 2021).

[14] https://www.whitehouse.gov/covidplan/ (last visited December 23, 2021).

[15] https://www.whitehouse.gov/covidplan/ (last visited December 23, 2021); https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard (last visited December 23, 2021); https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination (last visited December 23, 2021); https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited December 23, 2021).

far as to require COVID-19 vaccines for entry into restaurants, clubs, gyms, entertainment venues, and indoor events.[16]

19. While mandating this product, the federal government has also given the pharmaceutical companies selling these vaccines, and anyone associated with administering them, complete legal immunity for any injury caused by these vaccines. 42 U.S.C. § 247d-6d (providing that any "manufacturer" of "any vaccine, used to … prevent or mitigate COVID-19" shall be "immune from suit and liability under Federal and State law with respect to all claims … resulting from … [its] use by an individual"). These pharmaceutical companies are even immune from liability for willful misconduct unless the federal government, which promoted and licensed this product, first brings this claim. *Id.*

20. In response to another lawsuit filed by over 347 scientists, public health professionals and doctors seeking full disclosure of the data the FDA relied upon to license one of these vaccines, the federal government took the position that it needs at least 75 years to fully disclose that data to the public. The scientists, public health professionals and doctors sought this data in order to conduct an independent evaluation, akin to peer review.[17] Until all the data is fully released, they cannot perform this review since missing even one dataset could throw off any analysis.[18]

21. So, to be clear, Americans are forced to receive these vaccine products, but if injured, they cannot sue anyone associated with these vaccines, yet the government is refusing to permit outside scientists to review the pre-licensure data supporting their safety.

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[16] https://sf.gov/information/vaccine-required (last visited December 23, 2021); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited December 23, 2021).

[17] *See* www.phmpt.org.

[18] *See Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, 4:21-cv-01056-P (N.D. Tex.), ECF Nos. 26 and 31.

B. Vaccine Safety Monitoring

22. Because COVID-19 vaccines are being mandated for millions of Americans, it is essential that our federal health agencies ensure that these products are safe and afford the American people transparency regarding the data supporting that claim.

23. The CDC is one of the primary federal agencies responsible for monitoring vaccine safety, including the safety of COVID-19 vaccines. The CDC claims that "COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**[.]"[19]

24. One of the ways the CDC claims to monitor the safety of COVID-19 vaccines is through v-safe,[20] which "uses text messaging and web surveys to give personalized health check-ins after [one] receives a COVID-19 vaccine."[21] The app allows users to "quickly tell CDC if [they] have any side effects after getting a COVID-19 vaccine[,]" which "helps CDC monitor the safety of COVID-19 vaccines in near real time."

25. On May 20, 2021, the CDC published a document titled "V-safe active surveillance for COVID-19 vaccine safety" (the "**V-Safe Protocol**").[22] The document explains that "[t]he purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[23]

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[19] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (last visited December 27, 2021).

[20] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html (listing v-safe as one of the ways "CDC expanded and strengthened the country's ability to monitory vaccine safety") (last visited December 27, 2021).

[21] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html (last visited December 23, 2021).

[22] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf (last visited December 23, 2021).

[23] *Id*. at 3.

26. The V-Safe Protocol indicates that "V-safe data will be collected, managed, and housed on a secure server by Oracle."[24] The V-Safe Protocol further provides:

> **Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting.** CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the secure server.[25]

The V-Safe Protocol further states, "No PII [personally identifiable information] will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests."[26]

27. The CDC's V-Safe Protocol stresses the importance of this data and that it "is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports."[27] Despite these claims, deidentified v-safe data is not yet available to the public.

28. To ensure that the CDC acts in furtherance of its commitment to "openness and accountability" and to gain access to critical data regarding the safety of COVID-19 vaccines, Plaintiff made three separate FOIA requests to the CDC for information regarding v-safe including, but not limited to, the deidentified data in Oracle's possession.

C. The First Request (IR#0519)

29. On June 24, 2021, Plaintiff issued the First Request to the CDC seeking:

> **All de-identified data submitted to v-safe since January 1, 2020.**

(**Exhibit 1**.)

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[24] *Id.* at 8.

[25] *Id.* at 9 (emphasis added).

[26] *Id*. at 10.

[27] *Id*. at 12.

30. On June 29, 2021, the CDC issued a letter to Plaintiff and assigned #21-01506-FOIA to the First Request. (**Exhibit 2**.)

31. On July 29, 2021, the CDC issued a final response to Plaintiff and stated:

> **A search of our records failed to reveal any documents pertaining to your request. The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) communicated that the v-safe data contains approximately 119 million medical entries. The information in the app is not de-identified.**

(the "**First Response**"). (**Exhibit 3**.)

32. The First Response acknowledges that data has been submitted to v-safe: approximately 119 million medical entries exist. Plaintiff requested that data in de-identified form, recognizing that personally identifying information may be exempt from disclosure. The First Request captures data submitted to v-safe and subsequently de-identified by the CDC or by Oracle.

33. Therefore, on August 25, 2021, Plaintiff appealed the First Response on the basis that the CDC failed to conduct an adequate search for the requested records (the "**First Appeal**"). (**Exhibit 4**.) Plaintiff pointed out, *inter alia*, that the CDC's own documentation makes plain that "Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, **will have access to aggregate deidentified data for reporting**." *Id* at 3. Plaintiff therefore repeated its request that this deidentified v-safe data be made available to the public forthwith.

34. On August 27, 2021, HHS acknowledged the First Appeal and assigned it Tracking No. 2021-00256-A-PHS. (**Exhibit 5.**)

35. To date, neither HHS nor the CDC have substantively responded to the First Appeal. Therefore, Plaintiff is deemed to have exhausted its administrative remedies. *See* 5 U.S.C. § 552(a)(6)(C)(i).

D. The Second Request (IR#0522)

36. On June 24, 2021, Plaintiff issued the Second Request to the CDC seeking:

> **All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same.**

(the "**Second Request**"). (**Exhibit 6**.)

37. On June 29, 2021, the CDC issued a letter to Plaintiff and assigned #21-01507 to the Second Request. (**Exhibit 7**.)

38. On August 2, 2021, the CDC issued a final response to the Second Request and stated:

> **We located 61 pages and one Excel Spreadsheet of responsive records. After a careful review of these pages, no information was withheld from release.**

(the "**Second Response**"). (**Exhibit 8**.)

39. Despite the breadth of the request, the CDC's production was limited to the May 20, 2021 V-safe Protocol, noted as version 3, and one excel data dictionary. This production is woefully deficient, including because it did not include any communications sought as part of the Second Request. Therefore, on October 28, 2021, ICAN appealed the Second Response on the basis that the CDC failed to conduct an adequate search for the requested records (the "**Second Appeal**"). (**Exhibit 9**.)

40. On November 2, 2021, HHS acknowledged the Second Appeal and assigned it Case No. 2022-00010-A-PHS. (**Exhibit 10**.)

41. To date, neither HHS nor the CDC have substantively responded to the Second Appeal. Therefore, Plaintiff is deemed to have exhausted its administrative remedies. *See* 5 U.S.C. § 552(a)(6)(C)(i).

E. The Third FOIA Request (IR#0547)

42. On September 1, 2021, Plaintiff submitted a third FOIA request to the CDC in an effort to clarify the First Request based on the agency's response, and requested that the CDC:

> **Produce all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward.**

(the "**Third Request**"). (**Exhibit 11**.)

43. On September 3, 2021, the CDC issued a letter to Plaintiff and assigned #21-02128 to the Third Request. (**Exhibit 12**.)

44. Also on September 3, 2021, the CDC issued a second letter to Plaintiff stating that the Third Request "is a duplicate of" the First Request "and therefore has been administratively closed as a duplicate request." (**Exhibit 13**.)

45. Counsel for Plaintiff communicated with the CDC via email regarding the agency's administrative closure of the Third Request, but the CDC did not reverse its decision to close same. (**Exhibit 14**.)

46. The CDC did not inform Plaintiff of its right to seek assistance from the FOIA Public Liaison or its right to appeal. *See* 5 U.S.C. § 552(a)(6)(A)(i). *See also Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 65 (D.C. Cir. 1990) ("A response is sufficient for purposes of requiring an administrative appeal if it includes: the agency's determination of whether or not to comply with the request; the reasons for its decision; and notice of the right of the requester to appeal to the head of the agency if the initial agency decision is adverse."); *Shermco Indus. v Sec'y of U.S. Air Force*, 452 F.Supp. 306, 318 (N.D. Tex. 1978), *rev'd on other grounds*, 613 F.2d 1314 (5th Cir. 1980) (plaintiffs were not required to exhaust their administrative remedies when defendant failed to provide plaintiffs with a complete determination because defendant's response "does not include

a list of the releasable and withheld documents, does not include a statement of the fees charged for the releasable documents, and does not include a statement of why the agency believes waiver or reduction of any fee charged is not in the public interest or does not benefit the general public. The plaintiffs could not effectively appeal the . . . adverse decision on their FOIA request without this information."). Plaintiff has therefore exhausted its administrative remedies. *See* 5 U.S.C. § 552(a)(6)(C)(i).

HHS AND CDC FAILED TO TIMELY RESPOND TO PLAINTIFF'S APPEALS

47. Federal agencies must determine whether to comply with a FOIA request within 20 business days after receipt of such request. 5 U.S.C. § 552(a)(6)(A)(i). Similarly, federal agencies must "make a determination with respect to any appeal within" 20 business days after receipt of any appeal. 5 U.S.C. § 552(a)(6)(A)(ii). In "unusual circumstances," the 20-day period may be extended for no more than 10 business days "by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is to expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i).

48. In acknowledging the First Appeal and the Second Appeal, HHS informed Plaintiff that its appeals fell "under 'unusual circumstances' in that [its] office will need to consult with another office or agency that has substantial interest in the determination of the appeal." (**Exhibit 5**; **Exhibit 10**.) Despite the alleged "unusual circumstances," HHS was still obligated to "make a determination with respect to" the appeals no later than 30 business days after receipt of same. 5 U.S.C. § 552(a)(6)(B)(i).

49. More than 30 business days have elapsed since Plaintiff submitted the First Appeal and the Second Appeal, but Plaintiff still has not received a determination from the CDC on either appeal. Therefore, the CDC has failed to comply with the time limit provisions of FOIA.

CDC IMPROPERLY CLOSED THE THIRD REQUEST

50. Under FOIA, federal agencies are required to respond to requests for records that are reasonably described. 5 U.S.C. § 522(a)(3)(A). Records are "reasonably described 'if a professional employee of the agency familiar with the subject matter can locate the records with a 'reasonable amount of effort.'" *Freedom Watch, Inc. v. CIA*, 895 F. Supp. 2d 221, 228 (D.D.C. 2012).

51. In the First Response, the CDC claimed that data in the v-safe app is not deidentified. Therefore, to clarify the request, Plaintiff issued the Third Request and sought data submitted to v-safe that was **subsequently** de-identified (meaning, it was submitted by individuals with identifying information and at some point after that it was deidentified). The Third Request therefore reasonably described the requested records.

52. The CDC cannot claim that there are no records responsive to the First Request because "information in the app is not de-identified" while, at the same time, claiming that the request seeking data submitted to v-safe and **then** deidentified (either in response to the Third Request or otherwise) is duplicative of the First Request. The CDC's administrative closure of the Third Request is therefore inconsistent with the purpose of FOIA, which is "to pierce the veil of administrative secrecy and open agency action to the light of public scrutiny . . .." *Wis. Project v. United States DOC*, 317 F.3d 275, 279 (D. D.C. 2003) (internal quotation marks omitted).

53. It is public knowledge that the data submitted to v-safe already exists in a deidentified format and that data should be produced to Plaintiff and the public forthwith.

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an order directing the CDC to produce all deidentified v-safe data within one day from the date of any such order;

c. Enter an order directing the CDC to produce all other documents responsive to each of the FOIA Requests within 10 days from the date of any such order;

d. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

e. Grant such other and further relief as the Court may deem just and proper.

Dated: December 28, 2021

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